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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/932,605

08/17/2001

Aftab Alam

5073

7590

03/15/2004

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EXAMINER

QUAN, ELIZABETH S

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/932,605

Applicant(s)

ALAM, AFTAB

Examiner

Elizabeth Quan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☒ Claim(s) 5-8 and 16 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Drawings

1. The drawings are objected to because reference character (8), which represents the membrane, should be between frames (7) and (9) in FIG. 3A. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.
2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the frame-means provided with grid marking as recited in claim 10 and reservoir positioned on the multi-sample pipetting device as recited in claim 17 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: It is improper to describe the invention by inserting claim 19 into the SUMMARY OF THE INVENTION in the specification since the claim may change during the course of prosecution. On page 6, lines 15 and 20, "assemble" should be "assembled". On page 6, line 16, "frame means 7 & 8" should be "frame means 7 & 9". On page 6, line 21 "position" should be "positioned".

Appropriate correction is required.

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4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: micro-pore in claims 11 and 18. The specification describes the capillary opening as “micro-bore”.

Claim Objections

5. Claims 5-8, 16 are objected to because of the following informalities: “to be” should be inserted immediately before “asymmetrically placed” in claim 5. “the” immediately before “point of contacts” should be deleted in claim 6 and 7. “a” should be inserted immediately before “grid pattern” in claim 8. “the” immediately before “multi-sample pipetting devices” should be deleted in claim 8. “of the reservoir” should be deleted in line 1 of claim 8 since it currently does not make sense with “positions of the reservoir...arranged... such that it allows positioning of the reservoirs”. “in to open end” should be “into the open end” in claim 16.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the reservoir-rack provided with grid marking, does not reasonably provide enablement for the frame-means provided with grid marking. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification states

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that the reservoir-rack is marked with A & B on one side of the rack and C & D on the opposite side of the reservoir rack. The specification also indicates an arrow mark on the membrane and broken line which shown grid mark on the membrane. Is the broken line grid mark just an imaginary mark formed by aligning a letter (A, B, C, D) with the arrow on the membrane? Nevertheless, the specification never indicates that the frame-means is provided with grid marking.

8. Claim 17 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the positions of the reservoir in the reservoir-rack arranged in a grid pattern compatible with the application heads of the multi-sample pipetting devices, does not reasonably provide enablement for the reservoir to be positioned on the multi-sample pipetting device for taking an aliquot of liquid sample through the capillary opening. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification never states that the reservoir may be positioned on the multi-sample pipetting device.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 6 and 7 are rendered indefinite by the recitation of “said reservoir-rack is provided with a means to position the reservoir-rack **into** the device” since parent claim 1 recites the

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reservoir-rack as part of the device. How can the reservoir-rack be placed into the device, which comprises of a reservoir, frame-means, and reservoir-rack itself? It is also unclear how alternative footprints can be made when the reservoir has a set footprint. Examiner has interpreted this claim as being able to produce different patterns of drops onto the membrane.

12. Claims 3, 5-7, 10 add limitations directed toward a plurality of reservoirs when parent claim 1 only claims "a reservoir".

13. Regarding claims 1, 9, 10, 19, the word "means" is preceded by the word(s) "frame" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1, 2, 6, 7, 9, 11, 13-16, 18, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,317,726 to Shepel (embodiment of figs. 1, 2).

Shepel discloses a device for application of liquid sample on a membrane (10) (abstract; figs. 1, 2). A plurality of reservoirs (20) is formed within a reservoir-rack (12) for easy manipulation of positioning a plurality of reservoirs above the membrane surface (figs. 1, 2). A frame (2) is provided for locking engagement with the reservoir-rack by thumb screws (42) in

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threaded holes (62) (figs. 1, 2). Each reservoir has an open end (14) and an end opposite the open with an opening (18) wherein the open end is adapted to receive liquid samples (figs. 1, 2). It appears that opening (18) is a capillary opening. According to Merriam-Webster Collegiate Dictionary, a capillary opening is a very small bore. It appears that opening (18) is a very small bore. Samples may be loaded into the reservoir through the open end by a pipettor (figs. 1, 2). The reservoirs are capable of being aligned with the heads of a multi-sample pipetting device (figs. 1, 2). The capillary opening of the reservoir allows flow of the liquid sample from the reservoir into the membrane by capillary action since one would expect that there would be some capillary action in transferring liquid from the reservoir to the membrane. The capillary opening of the reservoir allows flow of the liquid sample from the reservoir into the membrane by centrifugal action since such action would more quickly urge the flow from the reservoir into the membrane. The capillary opening of the reservoir may be considered a micro-pore opening protruding as a capillary tip from the main body of the reservoir since Applicant has not provided a definition of a micro-pore opening in the instant application. The capillary opening of the reservoir touches and contacts the membrane (figs. 1, 2). Note that the reservoir rack may be shifted over infinite positions over the membrane within the frame to produce infinite patterns of drops on the membrane.

16. Claims 1-3, 5-7, 9, 11, 13-19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,317,726 to Shepel (embodiment of fig. 8).

Shepel discloses a device for application of liquid sample on a membrane (120) comprising an assembly of a plurality of reservoirs (142), frame-means (4,24,120) for securing the membrane for application of liquid samples, and reservoir-rack (122) with through-holes

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(140) for positioning the reservoirs in the reservoir-rack above the membrane surface (fig. 8).

The reservoir has an open end and an end opposite the open end with an opening (fig. 8). It appears that the opening is a capillary opening. According to Merriam-Webster Collegiate Dictionary, a capillary opening is a very small bore. It appears that the opening is a very small bore. The capillary opening touches and contacts the membrane (fig. 8). The open end is adapted to receive liquid samples and/or liquid pipetting devices through the open end for aliquoting the liquid sample through the capillary opening (figs. 1 and 2). The capillary opening of the reservoir may be considered a micro-pore opening protruding as a capillary tip from the main body of the reservoir since Applicant has not provided a definition of a micro-pore opening in the instant application. The capillary opening of the reservoir allows flow of the liquid sample from the reservoir into the membrane by capillary action since one would expect that there would be some capillary action in transferring liquid from the reservoir to the membrane. The capillary opening of the reservoir allows flow of the liquid sample from the reservoir into the membrane by centrifugal action since such action would more quickly urge the flow from the reservoir into the membrane. Since the reservoirs are pipette tips, they may be positioned on the pipette.

The reservoir-rack has a plurality of through-holes or positions that would allow one to asymmetrically place reservoirs. The positions of the reservoirs in the reservoir rack are arranged in a grid pattern that allows positioning reservoirs in columns and rows compatible with the application heads of multi-sample pipetting devices common in the field and industry, including multi-channel pipettors (fig. 8). Note that the reservoir rack may be shifted over infinite positions over the membrane within the frame to produce infinite patterns of drops on the

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membrane. The frame-means is provided with a means to secure the membrane in the frame-means and position the membrane opposite the reservoir-rack (fig. 8).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. Claims 1-5, 8, 9, 11, 13-19 are rejected under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 5,011,779 to Maimon in view of U.S. Patent No. 4,317,726 to Shepel.

Maimon discloses a device for application of liquid sample on a membrane (4) comprising an assembly of 96 reservoirs (2), frame-means (3,21,22) for securing the membrane for application of liquid samples, and reservoir-rack (1,5) with 96 through-holes (7) for positioning the 96 reservoirs in the reservoir-rack, such that the reservoirs are above the membrane surface (figs. 1 and 2; col. 4, line 41-col. 6, line 7; col. 6, line 43-col. 7, line 2). The reservoir has an open end and an end opposite the open end with an opening (figs. 1 and 2; col. 4, line 41-col. 6, line 7; col. 6, line 43-col. 7, line 2). The open end is adapted to receive liquid

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samples and/or liquid pipetting devices through the open end for aliquoting the liquid sample through the opening (figs. 1 and 2). It appears that the opening is a capillary opening.

According to Merriam-Webster Collegiate Dictionary, a capillary opening is a very small bore.

It appears that the opening is a very small bore. The capillary opening of the reservoir may be considered a micro-pore opening protruding as a capillary tip from the main body of the reservoir since Applicant has not provided a definition of a micro-pore opening in the instant application. The capillary opening of the reservoir allows flow of the liquid sample from the reservoir into the membrane by capillary action since one would expect that there would be some capillary action in transferring liquid from the reservoir to the membrane. The capillary opening of the reservoir allows flow of the liquid sample from the reservoir into the membrane by centrifugal action since such action would more quickly urge the flow from the reservoir into the membrane. Since the reservoirs are pipette tips, they may be positioned on the pipette.

The reservoir-rack has a plurality of through-holes or positions that would allow one to asymmetrically place reservoirs. For instance, the reservoirs of fig. 1 are asymmetrically placed since the sides lying next to the line of symmetry, which is defined as the line between rows D and E, are not mirror images as the through-holes of row G are completely filled with reservoirs while the through-holes of row B are partially filled with reservoirs. The same observation may be made from the perspective of the line of symmetry between columns 6 and 7 in which more through-holes in column 2 are filled with reservoirs than through-holes of column 11. The positions of the reservoirs in the reservoir rack are arranged in a grid pattern that allows positioning reservoirs in columns and rows compatible with the application heads of multi-sample pipetting devices common in the field and industry, including multi-channel pipettors,

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since the positions are arranged in the standard format of 8 rows with 12 wells in each row which conforms with existing automation (col. 3, line 27-col. 4, line 2; col. 4, line 67-col. 5, line 9; col. 6, line 52-col. 7, line 2). Furthermore, Maimon discloses that a 12-tip multi-channel pipette is used to transfer samples onto the membrane (col. 6, line 52-col. 7, line 2). The frame-means is provided with a means to secure the membrane in the frame-means and position the membrane opposite the reservoir-rack (col. 5, lines 33-65).

Maimon fails to disclose the capillary opening of the reservoir touching and contacting the membrane. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Maimon to use different pipette tips/dispensing tips/capillary syringe needles such that the capillary openings of the pipette tips/dispensing tips/capillary syringe needles touches and contacts the membrane since it is well known that contacting delivery tips with the membrane results in rapid, efficient, and more accurate delivery of liquid to the membrane as taught by Shepel.

20. Claims 11, 12, 14, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,317,726 to Shepel (figs. 1, 2, and 8) or U.S. Patent No. 5,011,779 to Maimon in view of U.S. Patent No. 4,317,726 to Shepel as applied to claims 1-5, 8, 9, 13-16, 17, 19 above, and further in view of U.S. Patent No. 6,045,325 to Kedar et al.

Shepel (figs. 1, 2, and 8) Maimon in view of Shepel fails to disclose that the capillary opening of the reservoir has an orifice narrow enough to prevent the free flow of liquid samples out of the reservoir under the force of gravity. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Shepel (figs. 1, 2, and 8) or Maimon in view of Shepel to provide an opening narrow enough to prevent

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free flow of the liquid samples out of the reservoir under the force of gravity to afford rapid and easy draining of the reservoirs without need for a centrifuge, vacuum manifold, or other complex or expensive accessory as taught by Kedar et al. (col. 12, lines 17-39).

21. Claims 4, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,317,726 to Shepel (figs. 1, 2, and 8).

Shepel fails to disclose the reservoir rack with at least 96 positions. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide 96 positions and multiples thereof since it is very well known to use plates with 96 wells for high-throughput assays and to conform with existing practices for more options of ancillary/accessory equipment.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (571) 272-1261. The examiner can normally be reached on M-F (8:00-4:30).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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